PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Wayne E. CORNISH et al.	)	Group Art Unit: 3736
	)	
Application No.: 09/746,144	)	Examiner: Jonathan M. Foreman
	)	
Filed: December 21, 2000	)	Confirmation No.: 2421
	)	
For: SUPERELASTIC GUIDEWIRE WITH LOCALLY ALTERED PROPERTIES	)	**VIA EFS WEB**
	)	

Attention: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 BOARD RULE § 41.41

Pursuant to 37 C.F.R. § 41.41, Appellants present this Reply to the Examiner's Answer dated July 8, 2009.

If any fees are required in connection with the filing of this paper, Appellants request that the required fees be charged to Deposit Account No. 06-0916.

REMARKS

I. Summary of the Claimed Subject Matter

Appellants agree with the Examiner's indication that claim 7 "only recites 'treating' . . ." the second section of the claimed superelastic member. Examiner's Answer, page 2. The specific manner of treating the second section recited in the "Summary of the Claimed Subject Matter" section of Appellants' brief filed March 16, 2009, i.e., "by atmospherically isolating a section of the superelastic member and alloying the second section by exposing the second section to a diffusible element" is not required by the language of claim 7. Rather, atmospheric isolation is but one of many methods that could be used to treat the claimed superelastic member with an easily diffusible element.

II. Evidence Relied Upon

The Examiner states that the following evidence was relied upon on this appeal: JP 04187159 ("Yamauchi"), U.S. Patent No. 5,722,981 ("Stevens"), U.S. Patent No. 6,325,766 ("Anderson"), U.S. Patent No. 6,428,317 ("Abel"), and U.S. Patent No. 6,969,397 ("Ginn"). *See* Examiner's Answer, page 3. While Appellants agree with the Examiner's citation of Yamauchi, Stevens, Anderson, and Abel, they strongly disagree with and traverse the Office's reliance on Ginn. Prior to the Examiner's Answer, Ginn was never cited or relied upon by the Examiner during the nearly nine (9) years of prosecution of this application. More importantly, the Examiner's reliance on Ginn gives rise to a new ground of rejection, and is therefore improper.

III. Grounds of Rejection

The Examiner indicates that two grounds of rejection are on appeal, i.e., a rejection of claims 7 and 20-26 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Anderson in view of Stevens, and a rejection of claims 7 and 21-25 under 35 U.S.C. § 013(a) as being allegedly unpatentable over Yamauchi in view of Abel. *See* Examiner's Answer, pages 3 and 4.

Appellants agree with the Examiner's identification of the obviousness rejection in view of Anderson and Stevens. However, Appellants disagree with the Examiner's identification of the obviousness rejection in view of Yamauchi and Abel, inasmuch as claims 7 and 22-26 were rejected by these references, not claims 7 and 21-25. *See id.* at 4; *See also* Appellants' brief filed March 19, 2009, page 9; Final Office Action dated May 28, 2009, page 3.

Further, as noted in the preceding section, the Examiner has cited an additional reference in the Examiner's Answer, namely U.S. Patent No. 6,969,397 to Ginn. While Ginn is not cited in either of the Examiner's grounds of rejection on appeal, it is relied on by the Examiner as evidence of allegedly "conventional materials" suitable for use as the proximal portion of the guide wires disclosed by Anderson. *See* Examiner's Answer, page 5, lines 14-15.

Although not clearly articulated, it is apparent that the Examiner is relying on Ginn's disclosure for the suggestion of guidewire materials that are <u>not</u> expressly or inherently taught by Anderson, namely Ginn's nickel-titanium materials. As discussed in more detail below, and contrary to the Examiner's position, Anderson actually teaches away from the use of the "conventional nickel-containing alloys" disclosed in Ginn.

Thus, the Examiner's reliance on Ginn in an attempt to provide a basis to modify the respective disclosures of Anderson and Stevens is not only a fundamental departure from the Examiner's position of record, but it forms an improper rejection under 35 USC §103(a).

Further, since Appellants presented no new arguments in the Appeal Brief filed March 19, 2009, the Examiner's introduction of a new ground of rejection in the Examiner's Answer is improper because it fails to provide Appellants with a opportunity to respond. *See* M.P.E.P. §1207.03 at § (II) (stating that "if an appellant has clearly set forth an argument in a previous reply during prosecution of the application and the examiner has failed to address that argument, the examiner would not be permitted to add a new ground of rejection in the examiner's answer to respond to that argument but would be permitted to reopen prosecution, if appropriate.")

Appellants understand that 37 C.F.R. § 41.39(b) identifies two options for appellants where an Examiner's Answer ". . . contains a rejection *designated as a new ground of* rejection . . . ." In the instant case, however, the Examiner's Answer does not "designate" a new ground of rejection. Appellants therefore believe that neither of the options specified by 37 C.F.R. § 41.39(b) are relevant to the situation in this case. Nonetheless, in an bona fide effort to appropriately respond, Appellants have presented responsive remarks to the Examiner's position in this Reply Brief.

IV. Response to Examiner's Answer

Contrary to the Examiner's myopic assertions, none of the references cited against the instant application teach or suggest each and every element of independent

claim 7. Specifically, none of the cited references teach or suggest, "[a]n elongated device . . . comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusable element, wherein said easily diffusable element is selected from the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy." Claim 7.

A. Anderson and Stevens do not teach or suggest each and every element of the claims 7 and 20-26.

1. Anderson

Anderson discloses a guidewire (10) having an elongated proximal portion (12) including a distal end (13) and a distal portion (14). *See* Anderson, column 2, lines 13-18 and 38-45. Distal end (13) is formed from "a substantially nickel-free high-nitrogen austenitic stainless steel alloy" (which is **not** super elastic). *See id.* Distal portion (14) is made from a "pseudo- or super-elastic [alloy] . . . such as nickel-titanium alloys." *Id.* In the alternative, Anderson discloses that **both** distal end (13) **and** distal portion (14) may be manufactured from ***stainless steel***, i.e., a material that is **not** superelastic. *See id.* at lines 48-50.

While Anderson mentions that "[o]ther suitable materials can also be used to form proximal portion 12 or distal portion 14 . . ." it specifies that such materials include "stainless steels . . . [and] cobalt based [alloys such as] Elgiloy[,]" i.e., additional materials that are **not** superelastic. *Id.* at lines 43-48. Indeed, Anderson is *silent* with respect to any elongated element comprising a superelastic member comprising an NiTi alloy and having adjacent first and second sections, wherein the second section has a

second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusible element selected from the group consisting of oxygen, hydrogen, and nitrogen, as claimed. *See* claim 7.

Consideration of Anderson's disclosure also reveals that the reference clearly does **not** support the Examiner's position. For example, the Examiner cites column 2, lines 38-62 of Anderson in support of a statement that the reference "disclose[s] an elongated medical device having a superelastic member (1) having a first section (12) with a first set of properties and an adjacent section (14) having a second set of properties." Examiner's Answer, page 3. However, these portions of Anderson describe an elongated member having a distal portion (14) which may be superelastic, and an adjacent distal end (13) which is formed from *stainless steel*, which again, is a material that is **not** superelastic. *See* Anderson, column 2, lines 38-62. Nowhere does Anderson describe an elongated element comprising a superelastic member comprising an NiTi alloy and having adjacent first and second portions, as claimed.

The Examiner's reliance on Anderson's discussion of the use of "conventional" materials to form proximal portion (12) does nothing to address the failure of the reference to teach or suggest a superelastic member in accordance with the pending claims. As explained above, Anderson mentions the use of "other suitable materials . . ." to form proximal portion 12 or distal portion 14, but immediately clarifies that those "other" materials are materials that do **not** exhibit superelasticity, such as stainless steel and cobalt based alloys. *See* Anderson, column 2, lines 43-48. The Examiner has failed to explain *why* one of ordinary skill would modify the proximal portion of Anderson's guidewire in an attempt to arrive at the claimed invention.

The Examiner relies on Ginn for the disclosure of superelastic NiTi as a supposedly "conventional" material for use in guide wires. *See* Examiner's Answer, page 5. Regardless of whether Ginn does or does not disclose the conventional use of nickel titanium alloys in guide wires, Anderson states that its invention "is directed to an . . . elongated guiding member comprising a core member formed from a *substantially nickel-free* high-nitrogen containing austenitic stainless steel alloy . . . [which] can have improved tensile and fatigue strength *as compared to conventional nickel-containing alloys* and improved ductility and fatigue strength as compared to high tensile strength alloys." Anderson, column 1, lines 50-57 (emphasis added).

In other words, Anderson is drawn to guide wires that include a proximal portion formed from nickel-free stainless steel alloys, precisely because such alloys exhibit beneficial properties relative to conventional nickel-containing alloys. *See id*. With this in mind, the Examiner has failed to explain *why* one of ordinary skill would replace the nickel-free steel forming proximal portion (12) of Anderson's guide wires with a *nickel containing* alloy such as superelastic NiTi, when Anderson specifically *teaches away* from the use of conventional nickel-containing alloys for the formation of proximal portion (12). It is well-established that it is improper to combine references if their combination would result in the destruction of the intended operation or if a reference teaches away from the claimed invention. See, *In re Laskowski,* 10 USPQ 2d 1397 (Fed. Cir. 1989).

2. Stevens does not cure the deficiencies of Anderson

Steven's does not cure Anderson's failure to teach or suggest an elongated device comprising a superelastic member within the scope of the pending claims. *See*

claim 7. Like Anderson, Stevens fails to teach or suggest a elongated device comprising a superelastic member comprising an NiTi alloy and having adjacent first and second sections. Indeed, the only superelastic members disclosed by Stevens are a "suture engaging loop 96" (*Id*. at column 3, lines 36-57) and a "suture engaging articulating loop 119" (*Id*. at column 5, lines 48-55), neither of which include two adjacent (superelastic) sections with different properties. Moreover, nothing in Stevens would suggest to one of ordinary skill in the art that Stevens' NiTi alloys, which are disclosed as useful for suture engaging loops, could be beneficially used to form proximal portion (12) of Anderson's guide wires. In particular, Stevens provides no information explaining *why* one of ordinary skill in the art would replace the *nickel-free* steel forming proximal portion (12) of Anderson's guide wires with a *nickel containing* alloy such as superelastic NiTi, when Anderson specifically *teaches away* from the use of conventional nickel-containing alloys for the formation of proximal portion (12).

Thus, the Examiner has failed to explain *why* one of ordinary skill would use Stevens' NiTi alloys, which are useful for suture engaging loops, to form proximal portion (12) of Anderson's guidewire. Such an explanation is particularly necessary in this case, given that Anderson specifically teaches away from the use of "conventional nickel-containing alloys," for forming proximal portion (12), instead favoring nickel-free stainless steels and their beneficial properties.

For at least these reasons and the reasons explained in Appellants' brief filed March 19, 2009, the 35 U.S.C. § 103(a) rejection of claims 7 and 20-26 as being unpatentable over Anderson and Stevens is improper, and should be withdrawn.

B. Yamauchi and Abel do not teach or suggest an elongated device comprising a superelastic member within the scope of claims 7 and 22-26

Contrary to the Examiner's position, Yamauchi and Abel do not teach or suggest an elongated device comprising a superelastic member within the scope of the pending claims, regardless of whether they are considered alone or in combination. In particular, these references fail to disclose an "elongated device . . . comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusable element . . . selected from the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy." Claim 7.

Rather, Yamauchi discloses a "core material for a catheter guide wire characterized as having a front end part and a base part configured so that they form an integrated part and being made up of a TiNi group shape-memorizing alloy wherein at least the abovementioned base part contains C [(carbon)]." Yamauchi, page 5, lines 6-10.[1] Yamauchi explains that carbon is added to the NiTi alloy of the base part for the purpose of improving the mechanical properties of the alloy. *See id.* at page 6, lines 6-12. In particular, Yamauchi states that "as long as the total amount of Ni+C is at least 50.0 at %, a good superelasticity can be obtained by the transformation temperature lowering effect brought about by adding the C." *Id.* at page 6, line 24-page 7, line 2. Yamauchi further discloses that when the amount of carbon is "less than 0.5 at%, the addition effect is slight[,]" whereas when it "exceeds 5.0 at %, problems with the

[1] All references to Yamauchi refer to the English Translation of the reference attached to the Examiner's Answer.

processing increase." *Id*. at page 7, lines 4-7. Yamauchi also explains that other parameters, such as aging temperature, must be optimized to avoid a decrease in the rigidity of the base part. *See id*. at lines 6-12.

Thus, Yamauchi is specifically drawn to the use of carbon containing NiTi as the base part of a guidewire, and the optimization of the alloy composition and processing parameters necessary for such an alloy to achieve a desired level of functionality. However, Yamauchi is silent with respect to an "elongated device . . . comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusable element . . . selected from the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy." Claim 7 (emphasis added).

The Examiner's assertion on page 6 of the Examiner's Answer that "Appellant cancelled . . . [carbon] from the claims once Yamauchi was applied as a reference," is irrelevant to the pending claims for a number of reasons, not the least of which being that Yamauchi provides no information that would suggest to one of ordinary skill in the art that the base part of the disclosed guide wires could be treated with another element, e.g., O, N, or H, and achieve the same desirable properties. That is, Yamauchi provides no information suggesting the equivalency of other elements, e.g., O, N, or H, to carbon in the NiTi alloys forming the base part of Yamauchi's guide wires.

In addition, to rely on equivalence as a rationale supporting an obviousness rejection (which the Examiner is apparently doing), the equivalency must be recognized in the prior art, and **cannot** be based on applicant's disclosure or the mere fact that the

components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. In the instant case, the Examiner has not supplied any evidence, apart from an improper reference to Appellants' disclosure, supporting an argument that carbon, oxygen, nitrogen, and hydrogen are equivalent additive elements for use in NiTi guide wires.

Abel does not cure the deficiencies of Yamauchi. Abel is drawn to *dental instruments*, such as endontic instruments used to enlarge root canals. *See* Abel, column 1, lines 8-10. Although Abel mentions that such instruments may be formed from NiTi alloys that include various additive elements, such as oxygen, nitrogen, iron, aluminum, chromium, cobalt, vanadium, zirconium, and copper, it is silent with respect to any superelastic element comprising an NiTi alloy with two adjacent sections having different properties, as claimed. In fact, Abel never mentions diffusing any elements into NiTi, but focuses on alloying NiTi with the recited additives, which is a fundamentally different process than diffusing. Furthermore Abel, like Yamauchi, provides no information suggesting the equivalency of other elements, e.g., O, N, or H, to carbon in the NiTi alloys forming the base part of Yamauchi's guide wires.

Thus, the Examiner has failed to explain *why* one of ordinary skill would modify the NiTiC base portion of Yamauchi's guide wires in an attempt to arrive at the claimed invention. Such an explanation is particularly necessary, given that Yamauchi expresses a strong preference for NiTiC, details various optimizations necessary for NiTiC to function in the disclosed application, and specifically indicates that if less than

0.5% of C is added to the alloy of the base portion, the desired properties (e.g., good superelasticity) will only be slightly obtained. *See* Yamauchi, page 6, line 6-page 7, line 12. In the instant case, however, the Examiner has not provided an adequate explanation as to *why* one of ordinary skill in the art would modify Yamauchi in an attempt to arrive at the claimed invention.

The Examiner takes the position that ". . . one of ordinary skill in the art . . . [would have been motivated] to modify the member as disclosed by Yamauchi . . . to include an easily diffusible element from the group consisting of oxygen, hydrogen and nitrogen as taught by Abel in order to allow a portion of the core to exhibit enhanced elastic properties." Examiner's Answer, page 6. The Examiner's position is flawed for at least two reasons.

First, nothing in Yamauchi or Abel suggests that an NiTi alloy that further includes H, N, or O will exhibit "enhance elastic properties" as alleged by the Examiner. As explained above, Yamauchi is silent with respect to such additional elements. Furthermore, Abel not only fails to mention diffusing the claimed additives into NiTi, but is vague as to the impact that such additives will have on NiTi (when alloyed, not diffused), stating only that such elements "can . . . have very significant effects on desired superelastic properties and performance of . . . [NiTi] materials." Abel, column 4, lines 10-12. Nowhere do the cited references explain that NiTi alloys containing O, H, or N will exhibit "enhanced elastic properties."

Second, and as explained above, neither Yamauchi nor Abel recognize the functional equivalency of other elements, such as O, N, and H, to carbon in the NiTi alloys forming the base part of Yamauchi's guide wires. Thus, neither of these

references suggest that NiTi alloys containing O, N, or H will exhibit *equivalent*, much less "enhanced elastic properties," relative to the NiTiC alloys of Yamauchi.

For at least the foregoing reasons and the reasons specified in Appellants' brief filed March 19, 2009, Appellants submit that the 35 U.S.C. § 103(a) rejection of claims 7 and 22-26 in view of Yamauchi and Abel is not tenable, and should be withdrawn

V. Conclusion

For the reasons of record and those set forth above, Appellants respectfully submit that the Office has failed to establish that claims 7 and 20-26 are obvious under 35 U.S.C. § 103(a). Appellants thus request that the rejections under 35 U.S.C. §103(a) be reversed and withdrawn.

Please grant any extensions of time required to enter this brief and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 8, 2009 By:_____
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